

Atty Dkt. No.: SKEL-012
USSN: 10/661,356

REMARKS

In view of the following remarks, the Examiner is requested to withdraw the rejections and allow Claims 1-2, 6-11, 18, 20-23 and 26, as well as newly added Claims 31 to 43, the only claims pending and under examination in this application.

Claims 1 and 11 have been amended to incorporate the limitations of dependent Claims 3, 4 and 5, which dependent claims have correspondingly been cancelled. New Claims 31 to 35 correspond to originally filed Claims 12 to 17. New Claims 36 to 43 find support in the originally filed claims, as well as page 13, lines 20 to 30, page 15, lines 13-15 and page 20, lines 14 to 20. Claims 18, 23 and 26 have been amended to specify that the vibratory element is a pneumatic vibratory element, support for this limitation being found in the specification at page 16, lines 3ff and Figs. 1 to 6. As no new matter is added by way of these amendments, entry of the amendments by the Examiner is respectfully requested.

The Office Action rejects Claims 1-5, 7-9, 11, 18-19, 23 and 26 under 35 U.S.C. § 102(b) as being anticipated by U.S. patent 6,149,655 (Constantz et al.).

In making this rejection, the Examiner points to the following passage of the '655 patent which reads:

Instead of, or in addition to, the application of pressure to the cement, cement delivery into and perfusion of the cement throughout the cancellous region of the compromised vertebral body being treated may be enhanced by applying external energy to the at least the region of cancellous bone where the presence of the calcium phosphate cement is desired. By external energy is meant physical energy, such as motion, which may be in the form of agitation, vibration, sonic wave and the like. Any means of introducing this external energy to the region of cancellous bone to be infiltrated may be employed. One convenient means of applying external energy to the region of the compromised vertebral body of interest is to vibrate the cement delivery means, where either the entire cement delivery means may be vibrated or just a portion of the delivery means may be vibrated, where preferably that portion of the delivery means proximal to the cancellous bone region of interest is vibrated, e.g. the delivery needle. Another means of introducing external energy to the desired site is to directly agitate the compromised vertebral body itself and/or the adjacent vertebral bodies. For example, to apply external energy directly to the compromised vertebral body, one may insert a second agitation device into the vertebral body. The amount of

Atty Dkt. No.: SKEL-012
USSN: 10/661,356

external energy which is introduced will not be excessive, but merely sufficient to promote efficient infiltration of the calcium phosphate cement composition throughout the cancellous bone region of interest.

Solely in order to expedite allowance of the present application, Claims 1 and 11 have been amended to include the limitation that delivery of the cement be done in conjunction with vibration in a manner such that penetration of the cement into the cancellous target site stops when vibration is stopped; and Claims 18, 23 and 26 have been amended to limit the vibratory element to a pneumatic vibratory element.

The claimed methods are based on the discovery by the inventors that vibration, when employed without substantial pressure, provides for tight control over delivery and penetration of an orthopedic cement to a target bone site, such as a vibratory body. Use of vibration provides for the ability to stop penetration of the cement at substantially the same time as vibration is removed.

As explained below, this finding was not predictable prior to this discovery by the inventors. In traditional delivery protocols, pressure is employed to provide the driving force for the cement into a target bone site. When pressure is stopped, the cement continues to penetrate and move into the target bone site for some time, which can result in significant health consequences, e.g., cement causing emboli upon unwanted movement into the circulatory system.

It was not known prior to the Applicants' work in this area that if vibration was used without substantial pressure, as currently claimed, one could obtain tight control over penetration of the cement into the vertebral body, e.g., by stopping vibration.

The above excerpt from the cited '655 patent fails to teach, or even suggest, this element of the claimed invention.

In the Office Action, the Examiner makes the unsupported conclusion that "Constantz et al. are utilizing vibration to enhance cement delivery. Thus, when vibration is stopped, perfusion of cement should also substantially stop."

Att'y Dkt. No.: SKEL-012
USSN: 10/661,356

However, as pointed out above, when pressure is employed as the driving force, removal of pressure does not cause penetration of the cement to immediately stop. Nothing in the '655 patent, or any other reference identified by the Examiner, would suggest that such behavior would not also be observed when vibration is used in delivery. As such, the Examiner's conclusion above is not supported by the '655 patent and does not necessarily flow from the teachings of the '655 patent.

Therefore, the '655 patent fails to teach (much less suggest) the element of the present claims that requires the cement to be delivered such that when vibration stops, cement penetration also stops.

With respect to Claims 18, 23 and 26, all of these claims require the use of a pneumatic vibratory element. Nothing in the '655 patent teaches or suggests such a vibratory element. Accordingly, the '655 patent does not anticipate the subject matter of these claims.

Therefore, Claims 1-5, 7-9, 11, 18-19, 23 and 26 are not anticipated under 35 U.S.C. § 102(b) by U.S. patent 6,149,655 and this rejection may be withdrawn.

The Office Action rejects Claims 18-21, 23 and 26 under 35 U.S.C. § 102(b) as being anticipated by U.S. patent 6,340,299 (Saito). As reviewed above, all of these claims require the presence of a pneumatic vibratory element. Saito fails to teach a pneumatic vibratory element. Accordingly, this rejection may be withdrawn.

The Office Action rejects Claims 10, 18-19, 23 and 26 under 35 U.S.C. § 102(b) as being anticipated by, or under 35 U.S.C. § 103(a) as being obvious over, U.S. patent 6,149,655. As reviewed above, the '655 patent is deficient in failing to teach or suggest a pneumatic vibratory element, which is an element of all of these claims but for Claim 10. With respect to Claim 10, the '655 patent fails to teach or suggest using vibration in conjunction with delivery such that penetration stops upon cessation of vibration, which is an element of Claim 10. As such, Claims 10, 18-19,

Atty Dkt. No.: SKEL-012
USSN: 10/661,356

23 and 26 are not anticipated by, or obvious over, the '655 patent and this rejection may be withdrawn.

The Office Action rejects Claim 6 under 35 U.S.C. § 103(a) as being obvious over U.S. patent 6,149,655 in view of U.S. patent 6,832,988. As reviewed above, the '655 patent is deficient in failing to teach or suggest the element of the claims that requires vibration to be used in a manner such that when the vibration is stopped, penetration of the cement also stops. As the '988 patent has been cited solely for its teaching of removal of diseased tissue by aspiration during vertebroplasty, the '988 patent fails to make up the fundamental deficiency in the '655 patent. As such, Claim 6 is not obvious under 35 U.S.C. § 103(a) over the '655 patent in view of the '988 patent and this rejection may be withdrawn.

Claims 19 and 26 have been provisionally rejected for statutory type double patenting under 35 U.S.C. § 101 over Claims 23 and 28 of copending application serial no. 10/797,907. In view of the amendment of Claims 23 and 28 of this copending application, this rejection may be withdrawn.

Claims 1-4 and 8 have been provisionally rejected under the judicially created doctrine of obviousness type double patenting over Claims 7-10 and 12 of copending application serial no. 10/900,019 in view of the '655 patent. In view of the enclosed Terminal disclaimer, this rejection may be withdrawn.

Claim 19 has been provisionally rejected under the judicially created doctrine of obviousness type double patenting over Claim 20 of copending application serial no. 10/900,019. In view of the enclosed Terminal disclaimer, this rejection may be withdrawn.

Finally, with respect to newly added Claims 31 to 35, these claims are patentable over the cited references for at least the reasons provided above. Furthermore, Claims 36 to 43 include the specification that the method result in the production of a cancellous bone/cement composite structure, a structure not taught

Atty Dkt. No.: SKEL-012
USSN: 10/661,356

or suggested by the cited art. Accordingly, these claims are also patentable over the cited references.

Atty Dkt. No.: SKEL-012
USSN: 10/661,356

CONCLUSION

In view of the amendments and arguments above, Applicants respectfully submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at (650) 327 3400.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-1078.

Respectfully submitted,

Date: June 24, 2005

By: 

Bret E. Field
Registration No. 37,620

enc:

- Terminal Disclaimer over application serial no. 10/900,019

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, CA 94301
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

E:\012\SKEL 012 Response to OA of 3-24-05.DOC